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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,670	11/28/2000	David Freundlich		9302

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EXAMINER
DAHBOUR, FADI H

ART UNIT	PAPER NUMBER
3742	

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,670	FREUNDLICH ET AL.	
	Examiner	Art Unit	
	Fadi H. Dahbour	3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-25* is/are rejected.

7)☒ Claim(s) *3-5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Examiner acknowledges Applicant's submission of the election of claims 1-25, filed on 10/21/02. Claims 26-38 being canceled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the processor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 6, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cline et al ('031).

Cline discloses a thermal treatment system (Figs.1-4), comprising a heat applying element for generating a thermal dose (330 of Fig.4) used to ablate a target mass in a patient (280 of Fig.4, also see "tumor" in line 1 of col.5), a controller for controlling thermal dose properties of the heat applying element (Fig.2), an imager for providing preliminary images of the target mass (see "magnetic resonance imaging...creates an image of the tissue" in lines 11-13 of abstract), a planner for automatically constructing a treatment plan (see "planning surgical procedures" in line 19 of col.1, also see "SURGICAL PLANNING" in Fig.2), comprising a series of treatment sites (see "heat is applied to tumor tissue 280 by periodically pulsing...heat source that creates heat over a line segment instead of a point" in lines 53-54, 61-62 of col.4) that are each represented by a set of thermal dose properties (see "frequency f and amplitude Q" in line 24 of col.5, and in lines 23-24 of col.6), wherein the treatment plan ensures that the entire target mass is covered by a series of thermal doses so as to obtain a composite thermal dose sufficient to ablate the entire target mass (see "to selectively destroy tumor 280" in lines 55-56 of col.4), wherein the heat applying element applies one of the following; ultrasound energy, laser light energy, RF energy, microwave energy and electrical energy (see "ultrasound transducer" in line 68 of col.4).

6. Claims 1-2, 6-7, 9, 11-16, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Acker et al ('522).

Acker discloses a focused ultrasound system (Figs.1-14), comprising a transducer for generating ultrasound energy that results in thermal doses used to ablate a target mass in a patient (see "ultrasound...transducers" in lines 39-40 of col.4), a controller for controlling thermal dose properties of the transducer (see "computer" in lines 59-67 of col.16, and in lines 1-17 of col.17, and in lines 12-17 & 30-32 of col.18, and in lines 1-29 of col.19, and in lines 50-63 of col.24), an imager for providing preliminary images of the target mass (see "image of the subject's tissues derived from the magnetic resonance information" in lines 16-17 of col.17) and for providing thermal images illustrating an actual thermal dose distribution in the patient (see lines 1-12 of col.19), and a planner for automatically constructing a treatment plan using the preliminary images, comprising a series of treatment sites represented by a set of thermal dose properties used by the controller to control the transducer (see lines 50-63 of col.24), wherein the planner further constructs a predicted thermal dose distribution illustrating the predicted thermal dose contours of each treatment site in the treatment plan (see "prediction" in lines 41-43 of col.24), wherein the imager further provides outlines of sensitive regions within the patient where ultrasonic waves are not allowed to pass (see "displaying a visual representation of the boundaries of the avoidance zone" in lines 46-47 of col.7), wherein the controller uses the outlines in constructing the treatment plan so as to avoid exposing the sensitive regions to ultrasound (see "the computer records the boundaries of...the avoidance zone" in lines 27-29 of col.19), wherein the sensitive regions comprise bones, gas, and other sensitive tissues (see "avoidance zone...tissues" in lines 13-14 of col.7), wherein the thermal dose properties

translate, at least in part, to electrical and mechanical properties of the heat applying element (see "computer actuates the energy application" in lines 18-19 of col.17, also see "electric power must be applied to the array to yield about 500 watts of ultrasonic emission" in lines 36-38 of col.13, also see "signals from the control computer into driver signals for the positioning system" in lines 16-17 of col.9), wherein the treatment plan ensures that the entire target mass is covered by a series of thermal doses so as to obtain a composite thermal dose sufficient to ablate the entire target mass (see "to heat the entire PFR" in line 41 of col.23), wherein the thermal dose properties are automatically optimized using physiological properties as the optimization criterion (see "optimized" in line 29 of col.13), wherein the treatment plan is constructed in three dimensions (see "three dimensional" in line 20 of col.16, and in line 29 of col.22), wherein the imager acts as a feedback imager for providing thermal images illustrating the actual thermal dose distribution resulting at each treatment site (see lines 1-12 of col.19).

7. Claims 1-2, 6-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Aida et al ('839).

Aida discloses a focused ultrasound system (Figs.1-14), comprising a transducer for generating ultrasound energy that results in thermal doses used to ablate a target mass in a patient (see "ultrasonic transducer" in line 10 of col.2), a controller for controlling thermal dose properties of the transducer (see "control circuit unit" in lines 26-36 of col.12, and in lines 22-30 of col.16), an imager for providing preliminary images of the target (see "image information containing the tumor 7 to be treated" in lines 20-21 of col.11), and for providing thermal images illustrating an actual thermal dose distribution in the patient (see "magnetic resonance imaging...can be used in checking the effect of the treatment and the temperature in a vicinity of the object" in lines 8-11 of abstract), and a planner for automatically constructing a treatment plan using the preliminary images, comprising a series of treatment sites represented by a set of thermal dose properties used by the controller to control the transducer (see "plan" in lines 33-45 of col.7, and in lines 18-28 of col.11, and in lines 26-36 of col.12), wherein the imager further provides outlines of sensitive regions within the patient where ultrasonic waves are not allowed to pass (see "avoidance of obstacles" in line 17 of col.11), wherein the controller uses the outlines in constructing the treatment plan so as to avoid exposing the sensitive regions to ultrasound (see "avoidance of obstacles in the...treatment plan" in lines 17-18 of col.11), wherein the sensitive regions comprise bones, gas, and other sensitive tissues (see "obstacles such as bones" in lines 35-36 of col.2), wherein the planner further constructs a predicted thermal dose distribution illustrating the predicted thermal dose contours of each treatment site in the treatment plan (see "plan" in lines 18-28 of col.11), wherein after a thermal dose is delivered to

each treatment site in the treatment plan, the actual thermal dose distribution is compared to the predicted thermal dose distribution to determine remaining untreated locations within the target mass (see "determine an untreated region of the tumor...by comparing...before and after" in lines 38-41 of col.7), wherein after a thermal dose is delivered to a treatment site in the treatment plan, the actual thermal dose distribution is compared to the predicted thermal dose distribution to determine changes to the dosing parameters in neighboring sonication sites (see "by comparing...before and after... further treatment can be automatically set to the determined untreated region" in lines 40-41, 44-45 of col.7), wherein the planner automatically evaluates the treatment plan based on the remaining untreated locations and updates the treatment plan to ensure complete ablation of the target mass is achieved by one or more of adding treatment sites, removing treatment sites, modifying existing treatment sites, or leaving the treatment plan unchanged (see "determine an untreated region of the tumor...further treatment can be automatically set to the determined untreated region" in lines 38-39, 44-45 of col.7), wherein a user can manually adjust the treatment plan based on the remaining untreated locations (see "but the manual control by the operator may also be provided...the operator should be able to revise the...treatment plan" in lines 29-30, 33-35 of col.12), wherein the preliminary images and the thermal images represent three-dimensional data (see "three-dimensional image information" in line 5 of abstract), wherein the predicted thermal dose distribution and actual thermal dose distribution represent three-dimensional data (see "three-dimensional image information" in line 5 of abstract), wherein the thermal dose properties translate, at least in part, to electrical

(see "driving the ultrasonic transducer 2 to generate the intense ultrasonic waves of a desired intensity" in lines 28-30 of col.5) and mechanical properties of the heat applying element (see "controlling a position" in line 31 of col.5), wherein the treatment plan ensures that the entire target mass is covered by a series of thermal doses so as to obtain a composite thermal dose sufficient to ablate the entire target mass (see "complete treatment of the entire tumor" in lines 2-3 of col.3), wherein the thermal dose properties are automatically optimized using physiological properties as the optimization criterion (see "optimal values" in line 64 of col.14), wherein the planner limits the thermal dose at each treatment site in order to prevent carbonization or evaporation (see "air bubbles" in line 44 of col.2), further comprising a user interface for entering user specified thermal dose prediction properties and for editing the treatment plan once the treatment plan is constructed (see lines 18-28 of col.11, and lines 26-36 of col.12), wherein the treatment plan is constructed in three dimensions (see "three-dimensional" in line 20 of col.11), wherein the imager acts as a feedback imager for providing thermal images illustrating the actual dose distribution resulting at each treatment site (see "checking the effect of the treatment and the temperature" in lines 10-11 of abstract).

Allowable Subject Matter

8. Claims 3-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ishibashi et al, Beach et al, Schaetzle et al, Fujimoto et al, Granz et al, Rolt et al, Oppelt et al, Do-huu et al and Pounds are cited to show ultrasound.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fadi H. Dahbour @ 703-306-5479 from 9AM to 5PM EST, or to Supervisor Teresa Walberg @ 703-308-1327, or to group fax numbers:

Before Final @ 703-872-9302

After Final @ 703-872-9303.

T. Walberg

Teresa Walberg
Supervisory Patent Examiner
Group 3700

November 6, 2002